

NOV 17 2006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Paul A. Price et al

Attorney Docket No.: UCSDP003.US

Application No.: 09/164,862

Examiner: Susan Unger

Filed: October 1, 1998

Group: 1642

Title: YKL-40 AS A MARKER AND
PROGNOSTIC INDICATOR FOR CANCERS**REQUEST FOR CONTINUED EXAMINATION (RCE)
(37 CFR §1.114)**Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

This is a Request for Continued Examination (RCE) of the above-identified application.

1. Submission required under 37 C.F.R. §1.114:

- a. ☒ Previously submitted
- i. ☒ Consider the amendment/reply under 37 C.F.R. §1.116 previously filed on October 6, 2006. *(Any unentered amendment referred to above will be entered.)*
- ii. ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____.
- iii. ☐ Other _____.
- b. ☒ Enclosed
- i. ☒ Amendment/Reply
- ii. ☐ Affidavit/Declaration
- iii. ☐ Information Disclosure Statement with Form PTO-1449
☐ Copies of IDS Citations
- iv. ☒ Other Copy of previously filed amendment.

11/20/2006 TL0111 00000025 500388 09164862
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2. **Fees:** (The RCE fee is required at the time the RCE is filed)

Fee Calculation (37 CFR §1.16)

Fee for Request for Continued Examination Under 37 C.F.R. §1.17(e)	\$790 =	790.00
TOTAL		790.00
SMALL ENTITY 50% FILING FEE REDUCTION (if applicable)		395.00

- ☐ a. Applicant hereby petitions for a _____ month extension of time.
- ☒ b. Applicant believes that no (additional) extension of time is required; however, if it is determined that such an extension is required, Applicant hereby petitions that such an extension be granted and authorizes the Director to charge the required fees for an extension of time under 37 CFR §1.136 to Deposit Account No. 500388.
- ☐ c. Enclosed is our Check No. _____ in the amount of \$ _____ to cover the RCE fee, extension of time and additional fees.
- ☒ d. The Director is authorized to charge any fees beyond the amount enclosed which may be required, or to credit any overpayment, to Deposit Account No. 500388 (Order No. UCSDP003.US)

- 3.
- ☒
- Please continue to send correspondence to the following address:

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Tom Hunter
Registration No. 38,498

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NO. 321- P. 4

Docket #	UCSDP003.US	By:	TXH.ca	Date	is mailing:	October 6, 2006
Serial #:	09/164,862	Filed:	October 1, 1998	Express Mail #	N/A	
Inv(s)	Paul A. Price et al					
Title:	YKL-40 AS A MARKER AND PROGNOSTIC INDICATOR FOR CANCERS					

The following have been received in the U.S. Patent Office on the date stamped hereon:

Item	Description	# Pgs
1.	Amendment Transmittal	1
2.	Amendment	8
3.	Check # 12446 (\$510.00)	1
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VOICE DATE	INVOICE NUMBER/REFERENCE	INVOICE AMOUNT	DISCOUNT	BALANCE
10/06/2006	UCSDP003 3 Months Extension Fee (\$510.00)	\$510.00	\$0.00	\$510.00

Check Number: 12446

Check Total: \$510.00

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(650) 981-8300

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Paul A. Price et al

Attorney Docket No.: UCSDP003.US

Application No.: 09/164,862

Examiner: Susan Unger

Filed: October 1, 1998

Group: 1642

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Title: YKL-40 AS A MARKER AND
PROGNOSTIC INDICATOR FOR CANCERS

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as first-class mail on October 6, 2006 in an envelope addressed to the Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.

Signed: _____


Cheryl Appleby

AMENDMENT TRANSMITTAL

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:


Transmitted herewith is an Amendment in the above-identified application.

The fee has been calculated as shown below.

	Claims After Amendment		Highest Previously Paid For	Present Extra	Small Entity Rate Fee	Large Entity Rate Fee
Total Claims		MINUS			x 25 =	x 50 =
Independent Claims		MINUS			x 100 =	x 200 =
Multiple Dependent Claim Present and Fee Not Previously Paid						
Total					\$	\$

- ☒ Applicant(s) hereby petition for a three month extension(s) of time to respond to the aforementioned Office Action.
- ☐ Applicant(s) believe that no (additional) Extension of Time is required; however, if it is determined that such an extension is required, Applicant(s) hereby petition that such an extension be granted and authorize the Commissioner to charge the required fees for an Extension of Time under 37 CFR 1.136 to Deposit Account No. 500388.
- ☒ Enclosed is our Check No. _____ in the amount of \$510.00 to cover the additional claim fee and/or extension of time fees.
- ☐ Please charge the required fees, or any additional fees required to facilitate filing the enclosed response, to Deposit Account No. 500388 (Order No. _____).

Respectfully submitted,
BEYER WEAVER & THOMAS, LLP


Tom Hunter
Reg. No. 38,498

P.O. Box 70250
Oakland, CA 94612-0250

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FACSIMILE COVER SHEET

November 17, 2006

Receiver: Examiner Susan Unger U.S.P.T.O.**TEL #:** 571-272-0837**FAX #:** 571-273-8300**Sender:** Tom Hunter**Our Ref. No.:** UCSDP003.US**Re:** Application Serial # 09/164,862**Pages Including Cover Sheet(s):** 14**MESSAGE:**

Enclosed: Request for Continued Examination
Copy of Previously Filed Amendment

PLEASE CONFIRM RECEIPT OF THIS FACSIMILE**CONFIDENTIALITY NOTE**

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Atty Docket No: UCSDP003US

Client Ref: 1998-298-1

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

PAUL A. PRICE and JULIA S. JOHANSEN

Examiner: Susan Ungar

Application No.: 09/164,862

Art Unit: 1642

Filed: 10/01/1998

**For: YKL-40 AS A MARKER AND
PROGNOSTIC INDICATOR FOR CANCERS****AMENDMENT**

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

INTRODUCTORY COMMENTS

Dear Sir:

In response to the Office Action dated March 15, 2006, Applicants respectfully request reconsideration of the above-identified application in view of the following amendments and remarks. A Notice of Appeal was filed on August 30, 2006. Accordingly, the following documents are enclosed herewith:

- 1) A petition to extend the period of response for three months;

Please amend the specification and/or claims as shown herein.

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AMENDMENTS TO THE CLAIMS

Claim 1 (Currently amended): A method for estimating survival expectancy of a cancer patient, said method comprising:

(a) obtaining a biological fluid sample comprising YKL-40 from a cancer patient having at least a preliminary diagnosis of a cancer selected from the group consisting of a lung cancer, a bronchus cancer, a colorectal cancer, a prostate cancer, a pancreas cancer, a stomach cancer, an ovarian cancer, a urinary bladder cancer, a brain or central nervous system cancer, a peripheral nervous system cancer, an esophageal cancer, a cervical cancer, a melanoma, a uterine or endometrial cancer, a cancer of the oral cavity or pharynx, a liver cancer, a kidney cancer, a biliary tract cancer, a small bowel or appendix cancer, a salivary gland cancer, a thyroid gland cancer, an adrenal gland cancer, an osteosarcoma, a chondrosarcoma, a liposarcoma, a testes cancer, and a malignant fibrous histiocytoma; and

(b) measuring the level of YKL-40 in said sample and comparing the sample YKL-40 level to the YKL-40 level found in the same sample from normal healthy humans wherein a sample YKL-40 level ~~in greater than the 95th percentile for YKL-40 levels in the same sample from~~ said normal healthy humans at a confidence level of 95% or greater is an indicator of a reduced survival expectancy compared to patients with normal YKL-40 level.

Claim 2 (Original): The method of claim 1, wherein said patient has a diagnosis of prostate cancer.

Claim 3 (Original): The method of claim 1, wherein said patient has a diagnosis of lung cancer.

Claim 4 (Original): The method of claim 1, wherein said patient has a diagnosis of a colorectal cancer.

Claim 5 (Original): The method of claim 4, wherein said patient is diagnosed with a Duke's stage A colorectal cancer.

Claim 6 (Original): The method of claim 4, wherein said patient is diagnosed with a Duke's stage B colorectal cancer.

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Claim 7 (Original): The method of claim 4, wherein said patient is diagnosed with a Duke's stage C colorectal cancer.

Claim 8 (Original): The method of claim 4, wherein said patient is diagnosed with a Duke's stage D colorectal cancer.

Claim 9 (Original): The method of claim 1, wherein said biological sample is a primary tumor or a tissue affected by the cancer.

Claim 10 (Original): The method of claim 1, wherein said biological sample is a sample selected from the group consisting of whole blood, plasma, serum, synovial fluid, cerebrospinal fluid, bronchial lavage, ascites fluid, bone marrow aspirate, pleural effusion, urine, and tumor tissue.

Claim 11 (Original): The method of claim 1, wherein the level of YKL-40 is measured by immunohistochemical staining of cells comprised within said biological sample.

Claim 12 (Original): The method of claim 11, wherein said cells are tumor tissue cells.

Claim 13 (Original): The method of claim 1, wherein the level of YKL-40 is measured using an immunoassay.

Claim 14 (Original): The method of claim 13, wherein said immunoassay is a competitive immunoassay.

Claim 15 (Original): The method of claim 13, wherein said immunoassay is an ELISA.

Claim 16 (Original): The method of claim 13, wherein said immunoassay is a radioimmunoassay (RIA).

Claim 17 (Original): The method of claim 13, wherein said immunoassay uses a polyclonal anti-YKL-40 antibody.

Claim 18 (Original): The method of claim 13, wherein said immunoassay uses a monoclonal anti-YKL-40 antibody.

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Claims 19-37 (Canceled).

Claim 38 (Currently amended): A method to screen for recurrence of a cancer after removal of a primary tumor, said method comprising:

(a) obtaining a biological fluid sample comprising YKL-40 from a cancer patient following removal of a primary tumor selected from the group consisting of a lung cancer, a bronchus cancer, a colorectal cancer, a prostate cancer, a pancreas cancer, a stomach cancer, an ovarian cancer, a urinary bladder cancer, a brain or central nervous system cancer, a peripheral nervous system cancer, an esophageal cancer, a cervical cancer, a melanoma, a uterine or endometrial cancer, a cancer of the oral cavity or pharynx, a liver cancer, a kidney cancer, a biliary tract cancer, a small bowel or appendix cancer, a salivary gland cancer, a thyroid gland cancer, an adrenal gland cancer, an osteosarcoma, a chondrosarcoma, a liposarcoma, a testes cancer, and a malignant fibrous histiocytoma; and

(b) measuring a level of YKL-40 in said sample and comparing the sample YKL-40 level to the YKL-40 level found in normal controls wherein a sample YKL-40 level greater than the 95th percentile for YKL-40 levels in normal controls at a confidence level of 95% or greater is an indicator of a possible recurrence of said cancer.

Claim 39 (Original): The method of claim 38, wherein said method is repeated at a multiplicity of instances after removal of said primary tumor.

Claims 40-46 (Canceled).

Claim 47 (Currently amended) A method of screening for an indicator for the presence of cancer, in a mammal, said method comprising:

(a) obtaining a biological sample comprising serum comprising YKL-40 from said mammal;

(b) measuring the level of YKL-40 in said serum and comparing the level to the YKL-40 level found in serum from normal healthy mammals, wherein elevation in YKL-40 at a confidence of 95% or greater than the 95 percentile level in the sample being tested compared to the sample from normal healthy mammals, wherein said elevation is unrelated to known causes of YKL-40 elevation other than cancer, is an indicator of the presence of a cancer selected from the group

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consisting of a lung cancer, a bronchus cancer, a prostate cancer, a pancreas cancer, a stomach cancer, an ovarian cancer, a urinary bladder cancer, a brain or central nervous system cancer, a peripheral nervous system cancer, an esophageal cancer, a cervical cancer, a melanoma, a uterine or endometrial cancer, a cancer of the oral cavity or pharynx, a liver cancer, a kidney cancer, a biliary tract cancer, a small bowel or appendix cancer, a salivary gland cancer, a thyroid gland cancer, an adrenal gland cancer, an osteosarcoma, a chondrosarcoma, a liposarcoma, a testes cancer, or a malignant fibrous histiocytoma.

Claim 48 (Canceled).

Claim 49 (Currently amended): The method of claim 47, wherein said biological sample is a sample selected from the group consisting of whole blood, plasma, and serum.

Claims 50-55 (Canceled).

Claim 56 (Original): The method of claim 47, wherein said mammal is a human.

Claim 57 (Original): The method of claim 47, wherein the level of YKL-40 is measured using an immunoassay.

Claim 58 (Original): The method of claim 57, wherein said immunoassay is a competitive immunoassay.

Claim 59 (Original): The method of claim 57, wherein said immunoassay is an ELISA.

Claim 60 (Original): The method of claim 57, wherein said immunoassay is a radioimmunoassay (RIA).

Claim 61 (Original): The method of claim 57, wherein said immunoassay uses a polyclonal anti-YKL-40 antibody.

Claim 62 (Original): The method of claim 57, wherein said immunoassay uses a monoclonal anti-YKL-40 antibody.

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Claim 63 (Previously presented): The method of claim 13, wherein said immunoassay comprises immunohistochemical staining.

Claim 64 (Previously presented): The method of claim 38, wherein the level of YKL-40 is measured using an immunoassay.

Claim 65 (Previously presented): The method of claim 63, wherein said immunoassay comprises immunohistochemical staining.

Claim 66 (Previously presented): The method of claim 47, wherein the level of YKL-40 is measured using an immunoassay.

Claim 67 (Previously presented): The method of claim 65, wherein said immunoassay comprises immunohistochemical staining.

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REMARKS

Status of the Claims.

Claims 1-18, 38, 39, 47, 49, and 56-67 are pending with entry of this amendment, claims 19-37, 40-46, 48, and 50-55 being previously canceled and claims 63-67 being previously added. Claims 1, 38, and 47 are amended herein. These amendments introduce no new matter. Support is replete throughout the specification, e.g., at page 28, line 32, through page 29, line 3, and the like.

Telephone interview with the Examiner.

Applicants thank Examiner Ungar for the courteous and productive telephone interview on September 26, 2006. In that interview discussions were drawn to the new matter rejection of record. Applicants pointed to pages 28-29 for support for an amendment drawn to a 95% confidence level rather than a 95% percentile level as recited in the claims prior to the present amendment. The Examiner indicated that it appears that the proposed amendment will overcome the rejection of the claims and will render the claims allowable.

35 U.S.C. §112, first paragraph.

Claims 1-18, 63, 65, and 67, were rejected under 35 U.S.C. §112, first paragraph, as the specification allegedly does not contain a written description for the language "greater than the 9th percentile for YKL-40" added to the claims in the previous amendment.

As discussed with Examiner Ungar, independent claims 1, 38, and 47 are amended herein to recite "... at a confidence level of 95% or greater. ..." rather than "... greater than the 95th percentile ...".

Applicants note that support for this amendment is found at page 28, line 32, through page 29, line 3 which states:

In a particularly preferred embodiment, the assay is deemed to show a positive result when the difference between sample and "control" is statistically significant (e.g. at the 85% or greater, preferably at the 90% or greater, more preferably at the 95% or greater and most preferably at the 98% or greater confidence level). [emphasis added]

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The amended claims thus clearly find support in the specification. Accordingly, the new matter rejection under 35 U.S.C. §112, first paragraph, should be withdrawn.

In view of the foregoing, Applicants believe all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. Should the Examiner seek to maintain the rejections, Applicants request a telephone interview with the Examiner. If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (510) 267-4161.

BEYER WEAVER & THOMAS, LLP
500 12TH STREET, SUITE 200
OAKLAND, CA 94607
TEL: (510) 663-1100
FAX: (510) 663-0920

Respectfully submitted,



Tom Hunter
Reg. No: 38,498

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NOV 17 2006

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Minneapolis, MN 55402-2215

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TO:

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450	FROM: Gregory A. Sebald OUR REF: 07500.0399USWO TELEPHONE: 612.336.4728
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Total pages, including cover letter: 2

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Title of Document Transmitted: Petition for Extension of TimeApplicant: WETTON et al.Serial No.: 10/362,706Filed: 29 August 2003Group Art Unit: 1634Our Ref. No. 07500.0399USWOConfirmation No. 3461

Please charge Deposit Account No. 13-2725 for the following item(s): \$1020.00 for Extension for response within third month.. Please charge any additional fees or credit overpayment to Deposit Account No. 13-2725. Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers, if appropriate.

By: Name: Gregory A. SebaldReg. No.: 33,280

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Casey CaronSignature Date 17 November 2006

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S/N 10/362,706

PATENTIN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: WETTON et al. Examiner: Bradley L. Sisson
Serial No.: 10/362,706 Group Art Unit: 1634
Filed: 29 August 2003 Docket No.: 07500.0399USWO
Title: IMPROVEMENTS IN AND RELATING TO MARKING

CERTIFICATE UNDER 37 CFR 1.6(d):

I hereby certify that this paper is being transmitted by facsimile to the U.S. Patent and Trademark Office on November 17, 2006.

By: 
Name: Casey Caron

PETITION FOR EXTENSION OF TIME

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

In accordance with the provisions of 37 C.F.R. §1.136(a), it is respectfully requested that a 3-month extension of time be granted in which to respond to the outstanding Office Action mailed 19 May 2006, said period of response being extended from 19 August 2006 to 19 November 2006.

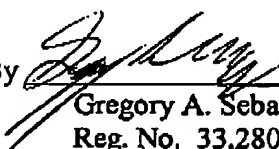
Please charge the Deposit Acct. No. 13-2725 in the amount of \$1,020.00 is to cover the required extension fee for a large entity.

Respectfully submitted,

MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, Minnesota 55402-0903
(612) 332-5300

23552
PATENT TRADEMARK OFFICE

Dated: 17 November 2006

By: 
Gregory A. Sebald
Reg. No. 33,280

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